

## REMARKS

Claims 1-33 are currently pending in the application. Claims 1, 2, 4, 13, 14, 18 and 24 have been amended. No new matter has been added. Reconsideration of the claims is respectfully requested. Amendments to the claims were made for the following reasons.

Regarding claim 1, the language "having a suitable size" and "being capable of" were removed and replaced with "being sized and adapted for". The Applicants submit that the amendment merely clarifies the language without narrowing the scope of the invention.

In claim 2, a minor grammatical error was corrected without narrowing the scope of the invention.

In claim 4, Applicants removed the language "capable of" in order to clarify the language without narrowing the scope of the invention.

In claim 13, the language "actuating elements" was removed and replaced with "being actuatable". Further, the word "projects" was changed to "projecting" to correct the grammatical tense of the claim without narrowing the scope of the invention.

Claim 18 was amended to clarify the grammatical tense of verbs in the claim and to specify that the opening of the cap is positioned over the pivot. The Applicants submit that the scope of the invention claims has not been narrowed.

In claim 24, trade names were removed and the elements making up the trade marked substances were substituted instead. Because the elemental composition corresponds to the trade marked product, the Applicants submit that the scope of the invention has not been narrowed.

In paragraph 1 on page 2 of the Office Action, the Applicants note that the drawings were objected to under 37 C.F.R. §1.83(a) as failing to show every feature of the invention as specified in the claims. According to the Office Action, Figs. 16, 20D, 21 and 25 have not been included and reference number 348 has not been disclosed in Fig. 15G.

The Applicants respectfully traverse the objections to the drawings. The Applicants filed 14 sheets of drawings with the application on October 23, 2000. Copies of the drawings as filed are enclosed for the Examiner's review and

convenience. Also attached is a copy of the return postcard showing a Patent and Trademark date stamp of October 23, 2000 indicating all 14 pages of drawings were received. The Applicants respectfully submit that Fig. 16 is located on the same drawing sheet disclosing Figs. 6 and 7; Figs. 20D and 25 are located on the same drawing sheet disclosing Fig. 20A; and Fig. 21 is located on the drawing sheet with Figs. 17 and 18.

Regarding reference number 348, on page 20 of the specification between lines 8 and 17, the Applicants' discussion is pointing back to Figs 15A-15F wherein the clip of Fig. 15G is also applicable. Reference number 348 is clearly disclosed in Figs. 15A-15F. The Applicants respectfully submit that all the features of the invention are clearly disclosed in the Applicants' 14 pages of drawings, and as such, request that the objections to the drawings under 37 C.F.R. §1.83(a) be withdrawn.

In paragraphs 3 and 4 on page 2 of the Office Action, claim 13 was rejected under 35 U.S.C. § 112 second paragraph for being indefinite. According to the Office Action, the limitation "an actuating element" is indefinite because it is unclear what the Applicants are claiming.

The Applicants respectfully traverse this rejection, but have removed the limitation from claim 13 in order to expedite prosecution in the Application. It is respectfully asserted that claim 13 complies with 35 U.S.C. § 112 and the rejection should therefore be withdrawn.

In paragraph 5 on page 2 of the Office Action, claim 24 was rejected under 35 U.S.C. § 112 second paragraph for using a trademark or trade name in the claim as a limitation to identify or describe a particular element of the claim.

The Applicants respectfully traverse this rejection, but have amended the application to overcome the rejection. Claim 24 has been amended by removing the words Elgiloy® and Nitinol® from the claims and substituting therefore the chemical compounds cobalt-chromium-nickel-molybdenum alloy and nickel-titanium alloy that respectively make up the above stated registered materials. It is believed that all claims comply with 35 U.S.C. § 112.

In paragraph 6 on page 3 of the Office Action, claims 1-13 were rejected under 35 U.S.C. §102 (e) as being anticipated by Laufer, et al. (U.S. 5,810,847) (Laufer).

According to the Office Action, Laufer discloses all the limitations set forth in Applicants' claimed invention.

To anticipate a claim, the reference must teach every element of the claim. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). Therefore, all claim elements, and their limitations, must be found in the prior art reference to maintain a rejection based on 35 U.S.C. §102. The Applicants respectfully submit that Laufer does not teach every element of claims 1-13, and therefore fails to anticipate claims 1-13.

Independent claim 1 is directed to a heart valve leaflet fastener including at least one pair of arms. The pair of arms are sized and adapted for fastening two adjacent heart valve leaflets. The arms pivot from one orientation to a gripping position and the ends of respective paired arms are directed toward each other.

In contrast to the Applicants' claimed invention, Laufer discloses a clip 15 having legs 40 and 42 having bends 44 located a distance from the ends of the legs 40, 42 to assist in clipping the valve cusps, as shown in Figs. 5-7, and ends directed away from each other, shown generally in the Figures.

Laufer is different from the Applicants' claimed invention at least because Laufer merely discloses bends located a distance from ends of the legs and ends of the legs pointing away from each other. In contrast, the invention of claim 1 includes arms directed toward each other at the ends thereof (see for example, Fig. 15G).

For at least the reasons set forth above, the Applicants respectfully assert that claim 1 is not anticipated by Laufer and is therefore allowable.

Dependent claims 2-13, which are dependent from independent claim 1, were rejected under 35 U.S.C. §102(b) as being unpatentable over Laufer. While Applicants do not acquiesce with the particular rejections to these dependent claims, it is asserted that these rejections are moot in view of the remarks made in connection with independent claim 1. These dependent claims include all of the limitations of the

base claim and any intervening claims, and recite additional features which further distinguish these claims from the cited references. Therefore, dependent claims 2-13 are also in condition for allowance.

In paragraph 6 on page 5 of the Office Action, claims 14-17 were rejected under 35 U.S.C. §102(b) as being anticipated by Bergman, et al. (U.S. 5,181,919) (Bergman). According to the Office Action, Bergman discloses all the limitations set forth in Applicants' claimed invention.

The Applicants respectfully submit that Bergman does not teach every element of claims 14-17, and therefore fails to anticipate claims 14-17 for the reasons set forth below.

Independent claim 14 is directed to a heart valve repair instrument including a ring and a ring applicator. The ring is releasably attachable to the applicator. The ring includes two pointed shafts. The applicator can apply a force to the ring to bring the points of the shafts toward each other relative to an initial position piercing and securing together respective heart valve leaflets. The ring and applicator have an appropriate size for placement within a chamber of a human heart.

In contrast to the Applicants' claimed invention, Bergman discloses a suture ligating device. Bergman discloses in Fig. 3 an elongated integral member 12 including elongated prongs 22 and 23 having curved ends ending in a suture carrying mechanism 16 and a suture grasping mechanism 17 to suture inside a body cavity. Bergman is at least different from the Applicants' claimed invention because Bergman merely discloses an elongated member having generally curved ends. In contrast, the invention of Applicants' claim 14 includes a ring and a ring applicator, and the ring being removably attachable to the ring applicator to pierce and secure together heart valve leaflets (see Figs. 34-37 and 39). Bergman merely provides means for suturing whereas the Applicants set forth a device for deploying a ring within a human heart (see Fig. 39).

For at least the reasons set forth above, the Applicants respectfully assert that claim 14 is not anticipated by Bergman and is therefore allowable.

Dependent claims 15-17, which are dependent from independent claim 14, were rejected under 35 U.S.C. §102(b) as being unpatentable over Bergman. While

Applicants do not acquiesce with the particular rejections to these dependent claims, it is asserted that these rejections are moot in view of the remarks made in connection with independent claim 14. These dependent claims include all of the limitations of the base claim and any intervening claims, and recite additional features which further distinguish these claims from the cited references. Therefore, dependent claims 15-17 are also in condition for allowance.

In paragraph 6 on page 6 of the Office Action, claims 18-22 and 24-33 were rejected under 35 U.S.C. §102 (e) as being anticipated by King, et al. (U.S. 3,874,388) (King). According to the Office Action, King discloses all the limitations set forth in Applicants' claimed invention.

The Applicants respectfully submit that King does not teach every element of claims 18-22 and 24-33, and therefore fails to anticipate claims 18-22 and 24-33.

Independent claims 18 and 30 are directed to a heart valve repair instrument at least including a cap and a gripper wherein the gripper comprises a plurality of arms radiating from a pivot with each arm having a spike. The opening in the cap being positioned over the pivot of the gripper locks the arms in a closed or collapsed gripping position.

In contrast to the Applicants' claimed invention, King discloses, in Figs. 7 and 8, an instrument for closing a defect in a heart wall including a plurality of struts 81, 91 attached to a hub 84. The struts 81, 91 are operable through a plurality of manipulating ties 7 connected to the struts 81, 91. King discloses that the struts may be covered by umbrella like elements 8, 9 for causing the struts to expand and open. King discloses in Fig. 8 that a loading cone 4 may be provided on the end of the catheter to collapse the struts and to permit entry of the instrument into the catheter.

King is different from the Applicants' claimed invention because King merely discloses an instrument having a central hub and a plurality of struts being openable via a plurality of manipulating ties. In contrast, Applicants' claim 18 is directed toward a heart repair instrument having a gripper having a plurality of arms connected at a pivot and a cap having an opening, wherein when the opening of the cap is positioned over the pivot, the arms are locked into a closed or collapsed gripping position (see for example, Figs. 15A-15F).

Further, the Applicants respectfully disagree with the Office Action's position that the umbrella-like structures 8 are a cap as disclosed in the Applicants' claimed invention. The umbrella-like structure 8 disclosed in King is unable to perform the function of positioning a cap over a pivot to lock a plurality of arms in a closed or collapsed position. Instead, the umbrella-like structure expands the struts in King to the fully open position (col. 8, line 67 through col. 9, line 6).

For at least the reasons set forth above, the Applicants respectfully assert that claim 18 is not anticipated by King and is therefore allowable. Claim 30 sets forth similar limitations as those set forth in claim 18 and is allowable for at least the same reasons given for claim 18 above.

Dependent claims 19-22, 24-29 and 31-33, which are dependent from independent claims 18 and 30, were rejected under 35 U.S.C. §102(b) as being unpatentable over King, respectively and claim 23 was rejected under 35 U.S.C. §103(a) over King. While Applicants do not acquiesce with the particular rejections to these dependent claims, it is asserted that these rejections are moot in view of the remarks made in connection with independent claims 18 and 30. These dependent claims include all of the limitations of their respective base claim and any intervening claims, and recite additional features which further distinguish these claims from the cited references. Therefore, dependent claims 19-29 and 31-33, are also in condition for allowance.

In view of the amendments and reasons provided above, it is believed that all pending claims are in condition for allowance. The Applicants respectfully request favorable reconsideration and early allowance of all pending claims.